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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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07/914,227 07/13/92 DE MEERE

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EXAMINER

KISHORE, G

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ART UNIT

PAPER NUMBER

1502

DATE MAILED: 11/17/92

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire -3- month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant; PTO-1449: -- | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152: -- |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 13 are pending in the application.
Of the above, claims 3 - 5 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1, 2, 6-8 and 10-13 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application; serial no. _____; filed on _____
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

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This application contains claims directed to the following patentably distinct species of the claimed invention:

1. composition containing gonadotropin dicarboxylic acid salts and non reducing sugar.

2. composition containing gonadotropin, dicarboxylic acid salts and non ionic gonadotropin, dicarboxylic acid salts and non ionic detergent.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 10-12 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be

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examined even though the requirement be traversed.

During a telephone conversation with William M. Blackstone on October 22, 1992 a provisional election was made without traverse to prosecute the invention of species 1, claims 2 and 6-8. Affirmation of this election must be made by applicant in responding to this Office action. Claims 3-5 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Claims included in the prosecution are 1, 2, 6-8 and 10-13.

Claims 1, 2, 6-8 and 10-13 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 6-8 and 11-12 recite dicarboxylic acid salts. Citric acid and isocitric acids are not dicarboxylic acids. Applicants' arguments that applicants may serve as their own lexicographer. The examiner would like to point out this is so, provided that the expression used are close to scientifically established terminology. A dicarboxylic acid totally different from a tricarboxylic acid. The examiner suggests "by weight of a salt of the acids selected from the group consisting of---". "delay a decrease" in claim 1 is indefinite. "delay" is a relative expression. The term should be replaced with time factor "source" in claims 1 and 8 should be specified.

"a second gonadotropin" in claim 7 and 10 is indefinite.
How is this distinguish from the first?

The units of "ionic strength" should be recited in claim 11.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 6-8 and 10-13 are rejected under 35 U.S.C. § 103 as being unpatentable over Koyama in view of Kawaguchi et al., Hamilton et al. and Hayashi et al.

Koyama teaches stabilized gonadotropin preparations containing an amino acid and a saccharide. The gonadotropin could be a recombinant one. The preparation is freeze dried (note the abstract and column 2, lines 10-166). Koyama does not however, teach the sugars and amino acid included in the generic teachings.

Kawaguchi while disclosing lyophilized erythropoietin preparations teaches the use of the combination of stabilizers, sucrose and citrates. (note the abstract; col. 1, line 64 - col. 2, line 14).

Hamilton et al. teach composition in a dry state containing growth hormones. Non-reducing sugars and citrates (note the abstract; col. 2, lines 58-60; col. 3, line 55 et seq., line 63 et seq.; col. 4, line 51 et seq.) Aspartate and glutamate are disclosed on col. 5, line 43 et seq.

Hayashi et al. while disclosing freeze dried preparation of

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Tumor Necrosis factor teach trehalose is a well known non-reducing sugar and a stabilizer (note the abstract).

Thus to include the specific sugars and acids taught by Kawaguchi, Hamilton and Hayashi in the generic teachings of Koyama would have been obvious to one of ordinary skill in the art since these components and their combinations are well known stabilizers for sensitive biologically active proteins.

Claims 1, 2, 6-8 and 10-13 are rejected under 35 U.S.C. § 103 as being unpatentable over Koyama in view of Kawaguchi et al., Hamilton et al. and Hayashi et al. cited for the reasons set forth above and further in view of Fernandes et al. Toray and Yasushi et al.

The obviousness of using a combination of sucrose and aspartic acid to stabilize sensitive, therapeutically active proteins and the use of, therapeutically active proteins and the use of sucrose or aspartic and in stabilizing proteins produced by recombinant means is further substantiated by the teachings of Fernandes et al. (note the abstract; col. 5, lines 1-25), Toray (note the abstract) and Yasushi (note the abstract and col. 2, lines 52-61)

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Any inquiry concerning this communication should be directed to G.S. Kishore at telephone number (703) 308-2440.

hsk
Kishore:css
November 04, 1992

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
ART UNIT 1502